PEC'H PCT/PTO 13 JAN 2005

Arrangement for increasing the stress resistance of implants, and one such implant.

1

- The present invention relates to an arrangement for increasing the stress resistance of implants arranged in an upper jaw bone. The invention moreover relates to an implant for this purpose and made of titanium or of another biocompatible material, for example ceramic.
- 10 In connection with implants, there is a need to be able to increase the implant's stability in the jaw bone so that the implant does not collapse after having been exposed for some time to stresses which arise, for example, during chewing movements. It is known, in this connection, that the stability can be increased by means of the length of the implant being increased, i.e. the implant being anchored in a greater mass of jaw bone.
- this from invention starts out present 20 understanding and proposes an arrangement and implants permitting this increase in length, which means that patients who for various reasons, for example poor upper jaw status, have hitherto been able to provided with implants only of short lengths, 25 example implant lengths of 7-8 mm, can now be provided with implants having greater lengths, for example 10 mm or more. With the previously known technique, patients even had to do without the fixtures implant question, due to the fact that the lengths which could 30 be used on the patients were too short. The invention solves these problems, among others, and allows the implant length to be increased in relation to what was previously possible, and more independently of, for example, the upper jaw status. 35

The feature which can principally be regarded as characterizing an arrangement according to the invention is, inter alia, that the implant has a length

- 2 -

which requires that the implant must be given access at parts to the sinus cavity and that the implant, at said parts, is arranged with a convex or rounded front surface which, upon access, lifts the sinus mucous membrane, without piercing the latter, and thus forms a closed space between the parts and the underside of the mucous membrane. The implant is provided, at least at said parts, with growth-stimulating substances which interact with cell-containing body fluid which has penetrated into the space, so that new bone is formed around said parts of the implant and thereby effects said resistance.

In a preferred embodiment, the convex or rounded front surface and at least one contiguous outer surface of the implant situated in the sinus are coated with layers of growth-stimulating substances. Said contiguous outer surface, and possibly at least parts of the front surface, are arranged with a rough outer layer or porous outer oxide layer(s) functioning as a reservoir for said growth-stimulating substance or substances. The roughness on the front surface is in this case designed not to cause penetration through the mucous membrane.

25

30

35

10

15

In one embodiment, the implant can be made of titanium and can be coated with growth-stimulating substance or substances, here called GSS, along most of its length. The growth-stimulating substance or substances can be matrix molecules, growth factors and differentiation growth-stimulating peptides with and/or factors properties. Other types of GSS can also be used. The implant can also be arranged in an upper jaw bone with reduced height, and the anchoring of the implant in the initial stage can in this case be complemented by anchoring elements, for example mechanical membranes, which can be connected to the outer surface of the upper jaw bone. After incorporation, the

- 3 -

anchoring is dependent on the degree of insertion of the implant in the sinus. The greater the degree of insertion, the greater the enclosed space, which means that the interacting body fluids and substances effect a greater formation of new bone around the implant.

The arrangement also comprises a member which can be introduced into a jaw bone hole extending from the outside of the jaw bone and opening into the sinus on the underside of the sinus mucous membrane. In the inserted position below said underside, the member is designed to effect a rotation movement as a function of a turning action, preferably of a manual type. The member has one or more front parts which are designed to be able to pass in between the boundary wall of the sinus and the underside of the mucous membrane and, upon said rotation movement or rotation movements, to free parts of the mucous membrane from the boundary wall of the sinus.

20

25

30

35

10

15

An implant according to the invention is characterized principally in that it is arranged with a convex or rounded front surface which can cooperate with the mucous membrane in the sinus, via the underside of the mucous membrane, to form an enclosed space between the implant and the underside of the mucous membrane. At least the parts which penetrate or have penetrated into the sinus are coated with growth-stimulating substance or substances arranged to interact with cell-containing body fluid in said enclosed space in order to form new bone around the front surface and the parts.

In a preferred embodiment, the parts of the implant on the outside in the sinus are designed with a roughened outer surface or porous outer oxide layer arranged to store said substance or substances.

- 4 -

By means of what has been proposed above, growthstimulating substance or substances (GSS) can be used effectively, and examples of GSS which may be mentioned molecules, growth factors matrix differentiation factors and/or peptides with growthaccordance with stimulating properties. In mucous membrane must be protected invention, the this is against mechanical action, and achieved effectively by the proposed lifting function, possible combination with the release function between the mucous membrane and the wall of the sinus. By means of what is proposed, it is possible to create an effectively enclosed space in which the cell-containing fluid can gain access and effectively interact with the GSS which is released from the implant.

10

15

20

25

A presently proposed embodiment of an arrangement and of an implant according to the invention will be described below with reference to the attached drawings, where

- Figure 1 shows, in vertical section, an implant which is fitted in a hole in the upper jaw bone and whose front parts have passed into the sinus and cooperate with the mucous membrane, at the underside thereof, so that a closed space for production of new bone is created,
- Figure 2 shows, in a vertical view, and enlarged in relation to Figure 1, the configuration of the front surface of the implant and parts penetrating into the sinus.
- Figure 3 shows, in vertical section, and enlarged in relation to Figure 2, parts of the front surface with applied growth-stimulating substance or substances,

- 5 -

Figure 4 shows, in vertical section, other parts of the implant's side surfaces which are coated with layers of growth-stimulating substance or substances, which outer sides can comprise one or more threads,

Figure 5 shows, in a vertical view, a second embodiment of the front surface of the implant,

10

5

Figure 6 shows, in vertical view, a third embodiment of the front surface of the implant, and

Figure 7 shows, in vertical section, members or instruments which, before lifting of the mucous membrane of the sinus, are intended to free the latter from the inner surface of the sinus.

In Figure 1, an upper jaw bone is represented by 1. A 20 hole 2 with an internal thread has been formed in the jaw bone. An implant 3 has been fitted in the hole in the jaw bone, its front parts 4a passing into a sinus 5. The insertion in this case is such that the front parts 4 have lifted the mucous membrane 6 of the sinus 25 by means of the implant's front parts 4 cooperating with the mucous membrane at the underside 6a thereof. It is important here that the lifting is done in such a way that the mucous membrane 6 is not pierced by the implant or is not damaged in a way which would involve 30 a risk of its later becoming pierced. The lifting of the-mucous membrane 6 results-in an enclosed space 7being formed between the underside 6a of the mucous membrane and the outer surface 4a of the outer parts. Body fluid 8 passes into the enclosed space from the 35 body tissue in accordance with arrows 9 and 10. At least said front parts 4 of the implant are provided, on said outer surface 4a, with growth-stimulating

substance or substances which interact with said body The substance or substances are initially fluid 8. applied in a specific amount and concentration on said surface 4a, and said interaction from said layer is represented in the figure by arrows 10. In Figure 1, 5 the formation of new bone has been symbolized by 11. Two stages have been indicated in the figure. In the first stage (see to the left of the front surface 4a), the body fluid accumulation and the initial interaction are indicated. In the second stage (see to the right of 10 the front parts 4), the completed formation of new bone is indicated. The figure also shows an inner surface la of the upper jaw bone, against which inner surface the underside 6a of the mucous membrane 6 bears before lifting. The implant can be of the self-tapping type or 15 of the type fitted in a previously formed thread in the jaw bone hole 2. In Figure 1, parts of an outer thread on the implant 3 have been indicated by 3a. Other parts of the implant can also be provided with amounts or growth-stimulating substance concentrations of 20 substances lying on the outside. Application of GSS to the implant 4 can be carried out in different ways, and with variations as regards the extent of the substance or substances along the length and circumference of the implant. The implant has a length L in accordance with 25 the above. The height or length L' of the dentine can vary as a function of the patient, jaw bone status, etc. The degree of insertion of the implant, i.e. L-L', is dependent inter alia on the length or height $\mathbf{L'}$. If the length or height is small, it may be important to 30 increase stability by means of the new bone formation in the_closed_space_7,_which-in-such_a_case_entails_a greater degree of insertion of the front parts 4a of the implant. The implant can be anchored to the jaw bone 1 temporarily or permanently using a mechanical 35 securing arrangement 12, for example a stiff membrane, which is secured with screws 13 in the jaw bone, at the outer surface 1b thereof. Alternatively, or in addition 5

- 7 -

to this, the membrane or reinforcement can be secured by a screw 12' which is screwed into an inner threaded hole in the implant. The design of the implant itself can be of a type known per se, and in this connection reference may be made to the "Branemark" system.

Figure 2 is an enlarged view showing the configuration of the front surface 4 in Figure 1. The front surface is designed with an evenness which avoids mechanical impact on the mucous membrane when the implant is 10 inserted into the sinus. The front surface can have a polished part 14 and, if appropriate, can be designed with a surface roughness or porous layer 14a at the sides. The surface roughness or porous layer in this case functions as a reservoir for layers of GSS. The 15 parts 4' contiguous to the front surface 4 can also be provided with said surface roughness or porous layer and can be charged with said GSS.

- Figure 3 shows the surface roughness 14 on the front 20 surface 4 in an enlarged view compared to Figure 2. A layer of GSS applied to the surface roughness is indicated by 15.
- In accordance with the above, the rest of the implant 3 25 can be coated completely or partially with GSS of a chosen amount and concentration 16. The thickness of the applied GSS can, for example, lie in the range of, for example, a few Angström to a few micrometers, a few nanometers. In the example according to Figure 4, a 30 coating has been applied to an outer thread 16 with a GSS_amount_or_GSS concentration_17._In_the_figures, the-GSS has been symbolized by broken lines 15, 16.
- In accordance with Figure 5, the front surface 4'' can 35 be designed in different ways. The front surface can be substantially plane or form an only slightly rounded front surface 18 which, at its periphery, has been

5

provided with bevels 18a, 18b so as not to cause damage to the aforementioned mucous membrane 6.

Figure 6 shows a further embodiment of the front surface 4''', which in this case has the basic shape of a sphere 19.

In accordance with Figure 7, the mucous membrane 6 can, at its underside 6a, be more or less firmly attached to or in the inner surface la of the upper jaw bone 1. In 10 this case it is advantageous to use a certain release function. The purpose of the release function is to free the mucous membrane 6 from the inner surface la before the lifting in accordance with Figure 1 is carried out. Said release can be done with the aid of 15 an instrument or member 20 which at its front part has a blade-shaped part 21. After passing through the jaw bone hole 22, said part 21 can be driven in between the inner surface la of the jaw bone and the underside 6a of the mucous membrane 6 so as to effect a release function between the jaw bone and the mucous membrane. Figure 7 shows this initial stage. The member 20 can be given a rotation movement 22 about its longitudinal axis 23, which results in the mucous membrane 6 being freed from the inner surface la around the mouth 2a 25 where the jaw bone hole opens into the sinus. In Figure 7, an initial stage for formation of the space 7 in Figure 1 has commenced. The initial space which has been created with the member 20 in the stage shown in indicated by 7'. Ιt 7 has been 30 appreciated that the member 20 and its insertion and releasing parts 21 can be designed in different ways. Thus, the member 20 can be provided with several parts 21. The parts can be arranged to be resilient relative to the longitudinal part 24 of the member. The part or 35 be provided with rounded surfaces can 21 cooperating with the mucous membrane 6 so that the latter is not damaged by the member 20 during the

- 9 -

initial release. The invention has been described above such that the mucous membrane 6 is considered as belonging to the sinus, like any space between the underside 6a of the mucous membrane and the top surface 1a of the jaw bone.

5

10

15

30

The invention is not limited to the embodiment shown above by way of example, and instead it can be modified within the scope of the attached patent claims and the inventive concept.

Reference may be made here to patent applications submitted to the Swedish patent office on the same day as the present patent application and by the same Applicant and inventor. Said applications have the following titles:

- a) "Arrangement for using osteoinductive or bioactive material to induce bone and/or increase the stability of implants in the jaw bone, and an implant intended for this purpose".
- b) "Arrangement for using bioactive or osteoinductive material to build up a bone-based lateral support for implants in the jaw bone".
 - c) "Arrangement for implants bearing growthstimulating substance or substances, and one such implant".

d) "Arrangement of two or more implants provided with growth-stimulating substance (s)".